#### REMARKS

According to a "Response to Request for Corrected Filing Receipt" mailed October 17, 2005, Applicants are required to supply in an Application Data Sheet or in an amendment to the specification, the continuity data of the instant application to earlier filed applications under 35 U.S.C. § 120, in order to obtain a corrected filing receipt.

In response, Applicants state that

- (i) a Preliminary Amendment, amending the originally-filed specification was filed July 30, 2003, to comply with requirements to claim priority to earlier filed applications.

  Applicants enclose a copy of said Preliminary Amendment together with a copy of the return receipt postcard acknowledging its delivery at the United States Patent and Trademark Office (EXHIBIT 1);
- (ii) in reviewing the Preliminary Amendment filed July 30, 2003, Applicants noted that the priority information disclosed therein contained an inadvertent error which has been addressed in the second preliminary amendment submitted herein. In particular, the relationship between International Patent Application No. PCT/US02/03087 as being a continuation-in-part of U.S. Patent Application No. 09/755,755 filed February 2, 2001, was not specified in the originally filed Preliminary Amendment, an inadvertent error which has been corrected in the presently filed Amendment; and
- (iii) Applicants have provided herewith a copy of: (A)the Response to Request for Corrected Filing Receipt mailed October 17, 2005; (B) a copy of the original filing receipt; and, (C) a copy of the original filing receipt containing redlined corrections indicating the corrected priority claim (EXHIBIT 2A-C).

Applicants request that the corrected priority of the instant application be made of record and the petition to issue a corrected Filing Receipt be granted following submission of the Second Preliminary Amendment herein.

In an abundance of caution, Applicants further request that this paper be considered a Petition To Correct Priority Date pursuant to 37 C.F.R. § 1.78(a)(3) due to unintentional delay in claiming priority to earlier filed applications, should the Commissioner so require. As noted in (i) above, Applicants had filed a Preliminary Amendment claiming priority to earlier filed application but inadvertently omitted reference to the relationship between two prior application i.e. International Patent Application No. PCT/US02/03087 being a continuation-in-part of U.S. Patent Application No. 09/755,755 filed February 2, 2001. Applicants state that the entire delay between the date the claim was due and the date the claim was (properly) filed was unintentional since the error in preliminary amendment filed July 30, 2003 was only recently noted after receiving the Response to Request for Corrected Filing Receipt mailed October 17, 2005. Applicants authorize the charging of the required fee of \$ 1,370.00 under 37 C.F.R. § 1.17(t) to deposit account 02-4377, should the Commissioner require filing of a Petition to Correct Priority pursuant to 37 C.F.R. § 1.78(a)(3) and consider this document as the Petition.

Applicants do not believe that any additional fee is required in connection with the submission of this document. Should any fees be required, the Commissioner is hereby authorized to charge any additional fees to Deposit Account 02-4377. A duplicate copy of this communication is provided.

Respectfully submitted,

BAKER BOTTS L.L.P.

By:

Lisa B. Kole Patent Office Reg. No. 35,225 (212)408-2628 direct dial

Attorney for Applicants

30 Rockefeller Plaza 44th Floor New York, New York 10112 212-408-2626



File Number: A33459-PCT-ÚSA-A specification, 5 page(s) of claims, 1 page(s) of abstract, 0 sheet(s) of drawings, a check in the amount of \$1,250.00 and a Deviation of approximation entitled "Combinations of Antiseptic and Antibiotic Agents That Inhibit the Development of Resistant Microorganisms"

10/633404 The stamp of the Patent Office Mail Room hereon acknowledges receipt on the date indicated by such stamp of patent application papers comprising 55 page(s) of in the amount of \$1,236.00 and a Declaration by applicant(s) S. Modak for an

Mailing Date: July 30, 2003

Comments: Information Disclosure Statement and References Cited, International Search Report; Unsigned Declaration; Preliminary Amendment

MAIL STOP PCT



## A33459-PCT-USA-A 070050.2439 PATENT

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant** 

Modak, et al.

Serial No.

To Be Assigned

Examiner:

To Be Assigned

Filed

July 30, 2003

Group Art Unit: To Be Assigned

For

COMBINATIONS OF ANTISEPTIC AND ANTIBIOTIC AGENTS

THAT INHIBIT THE DEVELOPMENT OF RESISTANT

**MICROORGANISMS** 

## PRELIMINARY AMENDMENT

July 30, 2003

# EXPRESS MAIL LABEL NO.: EV343636821US

Commissioner for Patents Box 1450 Alexandria, VA 22313-1450

:

#### Mail Stop PCT

Dear Sir:

Preliminary to the examination of the present application, please make the following amendments:

#### **AMENDMENTS TO THE CLAIMS**

- 1. (Original) An anti-infective medical article prepared by exposing a polymer-containing medical article, for an effective period of time, to a treatment solution comprising between 1 and 8 percent (weight/volume) of minocycline and between 1 and 8 percent (weight/volume) of a chlorhexidine compound.
- 2. (Original) The anti-infective medical article of claim 1, where the treatment solution further comprises a bismuth salt at a concentration of between 0.5 and 2.0 percent (weight/volume).
- 3. (Original) The anti-infective medical article of claim 1, where the treatment solution further comprises between 0.2 and 1.0 percent (weight/volume) benzalkonium chloride.
- 4. (Original) The anti-infective medical article of claim 2, where the treatment solution further comprises between about 0.25 and 1.0 percent (weight/volume) benzalkonium chloride.
  - 5. (Cancel)
  - 6. (Cancel)
- 7. (Original) The anti-infective medical article of claim 2 where the bismuth salt is bismuth citrate.
- 8. (Original) The anti-infective medical article of claim 4, where the bismuth salt is bismuth citrate.
- 9. (Original) The anti-infective medical article of claim 2, where the bismuth salt is bismuth salicylate.
  - 10. (Original) The anti-infective medical article of claim 4, where the bismuth

salt is bismuth salicylate.

- 11. (Currently Amended) The anti-infective medical article of claim 1, where the chlorhexidine compound is selected from the group consisting of chlorhexidine free base, chlorhexidine diacetate, chlorhexidine gluconate and mixtures thereof, a mixture of chlorhexidine gluconate and chlorhexidine free base, a mixture of chlorhexidine gluconate and chlorhexidine diacetate, a mixture of chlorhexidine gluconate, chlorhexidine free base and chlorhexidine diacetate.
- 12. (Currently Amended) The anti-infective medical article of claim 2, where the chlorhexidine compound is selected from the group consisting of ehlorhexidine free base, ehlorhexidine diacetate, chlorhexidine gluconate and mixtures thereof, a mixture of chlorhexidine gluconate and chlorhexidine free base, a mixture of chlorhexidine gluconate and chlorhexidine diacetate, a mixture of chlorhexidine gluconate, chlorhexidine free base and chlorhexidine diacetate.
- 13. (Currently Amended) The anti-infective medical article of claim 3, where the chlorhexidine compound is selected from the group consisting of chlorhexidine free base, chlorhexidine diacetate, chlorhexidine gluconate and mixtures thereof, a mixture of chlorhexidine gluconate and chlorhexidine free base, a mixture of chlorhexidine gluconate and chlorhexidine diacetate, a mixture of chlorhexidine gluconate, chlorhexidine free base and chlorhexidine diacetate, and a mixture of chlorhexidine free base and chlorhexidine diacetate.
- 14. (Currently Amended) The anti-infective medical article of claim 4, where the chlorhexidine compound is selected from the group consisting of ehlorhexidine free base, ehlorhexidine diacetate, chlorhexidine gluconate and mixtures thereof, a mixture of

NY02:451201.1 3

chlorhexidine gluconate and chlorhexidine free base, a mixture of chlorhexidine gluconate and chlorhexidine diacetate, a mixture of chlorhexidine gluconate, chlorhexidine free base and chlorhexidine diacetate, and a mixture of chlorhexidine free base and chlorhexidine diacetate.

- 15. (Original) An anti-infective medical article prepared by exposing a polymer-containing medical article, for an effective period of time, to a treatment solution comprising between 1 and 8 percent (weight/volume)of minocycline, between 1 and 8 percent (weight/volume) of triclosan, and a bismuth salt at a concentration of between 0.5 and 2.0 percent (weight/volume).
- 16. (Original) The anti-infective medical article of claim 15, where the treatment solution further comprises between 0.25 and 1.0 percent (weight/volume) benzalkonium chloride.
  - 17. (Cancel)
  - 18. (Cancel)
- 19. (Original) The anti-infective medical article of claim 15, where the bismuth salt is bismuth citrate.
- 20. (Original) The anti-infective medical article of claim 16, where the bismuth salt is bismuth citrate.
- 21. (Original) The anti-infective medical article of claim 15, where the bismuth salt is bismuth salicylate.
- 22. (Original) The anti-infective medical article of claim 16, where the bismuth salt is bismuth salicylate.

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23. (Original) An anti-infective medical article prepared by exposing a polymer-

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containing medical article, for an effective period of time, to a treatment solution comprising between 1 and 8 percent (weight/volume) of minocycline, between 0.25 and 1.0 percent (weight/volume) of benzalkonium chloride, and between 0.5 and 2.0 percent (weight/volume) of a bismuth salt.

- 24. (Currently Amended) The anti-infective medical article of claim 23, where the bismuth salt is selected from the group consisting of bismuth nitrate, bismuth citrate, and bismuth salicylate.
- 25. (Original) An intravascular catheter comprising between 100 and 450 micrograms of minocycline per centimeter and between 130 and 520 micrograms of a chlorhexidine compound.
- 26. (Original) The catheter of claim 25 further comprising between 50 and 300 micrograms per centimeter of a bismuth salt.
- 27. (Currently Amended) The catheter of claim 26 where the bismuth salt is selected from the group consisting of bismuth nitrate, bismuth citrate and bismuth salicylate.
- 28. (Original) The catheter of claim 26 further comprising between 25 and 100 micrograms per centimeter of benzalkonium chloride.
- 29. (Currently Amended) The catheter of claim 25 where the chlorhexidine compound is selected from the group consisting of chlorhexidine free base, chlorhexidine diacetate, chlorhexidine gluconate and mixtures thereof, a mixture of chlorhexidine gluconate and chlorhexidine free base, a mixture of chlorhexidine gluconate and chlorhexidine diacetate, a mixture of chlorhexidine gluconate, chlorhexidine free base and chlorhexidine diacetate, and a mixture of chlorhexidine free base and chlorhexidine diacetate.

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- 30. (Original) The catheter of claim 25 further comprising between 50 and 200 micrograms per centimeter of a zinc salt.
- 31. (Original) The catheter of claim 25 further comprising between 25 and 300 micrograms per centimeter of a silver-containing compound.
  - 32. (Cancel)
- 33. (Original) An intravascular catheter comprising between 100 and 450 micrograms of minocycline per centimeter, between 130 and 750 micrograms of triclosan per centimeter, and between 50 and 300 micrograms of a bismuth salt per centimeter.
- 34. (Currently Amended) The catheter of claim 33 where the bismuth salt is selected from the group consisting of bismuth nitrate, bismuth citrate and bismuth salicylate.
- 35. (Original) The catheter of claim 33 further comprising between 25 and 100 micrograms per centimeter of benzalkonium chloride.
- 36. (Original) The catheter of claim 33 further comprising between 50 and 200 micrograms per centimeter of a zinc salt.
- 37. (Original) The catheter of claim 33 further comprising between 25 and 300 micrograms per centimeter of a silver-containing compound.
  - 38. (Cancel)
- 39. (Original) An anti-infective medical article prepared by exposing a polymer-containing medical article for an effective period of time to a treatment solution comprising between 1 and 8 percent (weight/volume) of minocycline and between 0.5 and 2.0 percent (weight/volume) of a bismuth salt.

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#### **AMENDMENTS TO THE SPECIFICATION**

Please insert the following paragraph on page 1, after "SPECIFICATION" and before "INTRODUCTION" as follows:

# CROSS REFERENCE TO RELATED APPLICATION(S)

This application is a continuation of PCT Application No. PCT/US02/03087 which was filed on January 31, 2002, published on January 3, 2003 in English as International Publication No. WO 03/000303 and claims priority to U.S. Application No. 09/775,775, filed February 2, 2001, now issued U.S. Patent No. 6,582,719, all incorporated by reference in their entireties herein.

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#### **REMARKS**

This Preliminary Amendment amends the originally-filed specification of the above-referenced application, filed herewith as a continuation of International Application No. PCT/US02/03087, filed on January 31, 2002, published on January 3, 2003 as International Publication No. WO 03/000303 and claims priority to U.S. Application No. 09/775,775, filed February 2, 2001, now issued U.S. Patent No. 6,582,719.

Claims 1-4, 7-16, 19-31, 33-37, and 39 are currently pending and are presently under consideration in the above-identified application. Claims 5, 6, 17, 18, 32, 38 have been cancelled as directed to subject matter which has been allowed in U.S. Patent Application Serial No. 09/775,775, now US 6,582,719. Claims 11-14, 24, 27 and 34 have also been amended to eliminate reference to allowed subject matter in U.S Patent Application Serial No. 09/775,775, now US 6,582,719.

In addition, the specification has been amended to insert a reference to related applications. The amendments to the specification and the claims do not add new matter to the application.

## **CONCLUSION**

Applicants request an early and favorable decision on Claims 1-4, 7-16, 19-31, 33-37, and 39.

Respectfully submitted,

BAKER BOTTS L.L.P.

Henry Tang

Patent Office Reg. No. 29,705

Lisa B. Kole

9

Patent Office Reg. No. 35,225

Attorneys for Applicants (212) 408-2500



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| APPLICATION NUMBER   | FILING OR 371(c) DATE | FIRST NAMED APPLICANT       | ATTY. DOCKET NO./IITLE                   |
|--|-----------------------|-----------------------------|--|
| 10/633,204   | 07/30/2003            | BAKER BOTTS LLP<br>RECEIVED | A33459-PCT-USA-A<br>(070050. <b>2439</b> |
| 21003<br>BAKER & BOTTS<br>30 ROCKEFELLER PLAZA<br>NEW YORK, NY 10112 |                       | OCT 21 2005                 | CONFIRMATION NO. 3145                    |

Date Mailed: 10/17/2005

## RESPONSE TO REQUEST FOR CORRECTED FILING RECEIPT(SR POTTS L.L.P.

**Domestic Continuity and Foreign Priority** 

05 OCT 21 PM 4: 32

|                        | 1 RVTO  |
|------------------------|---|
| In respons<br>because: | se to your request for a corrected Filing Receipt, the Office is unable to comply with the request  |
|                        | The priority or continuity claim has not been entered because it was not filed during the required time period. Applicant may wish to consider filing a petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55 or 1.78.                                      |
| X                      | Continuity claimed under 35 U.S.C. § 120 cannot be added to the Filing Receipt without the applicant supplying the relationship (continuation, divisional, or continuation-in-part) in an Application Data Sheet or amendment to the first page of the specification.                   |
| Q                      | A claim for priority cannot be made based on an application filed after the application making the claim.   |
|                        | Domestic benefit and foreign priority claims will not be captured in a provisional application. A provisional application is not entitled to a right of priority or to the benefit of an earlier filing date of any other application. See 35 U.S.C. § 111(b)(7) and 37 CFR 1.53(c)(4). |
|                        | A domestic continuity claim cannot be made to a foreign application and the filing receipt will only list the foreign country, application number, and filing date.   |
| <u> </u>               | Foreign priority will appear on the Filing Receipt in the following order: Country, Application number, Filing date.  |
|                        | This application is the result of a conversion from a provisional application. Priority based on such application cannot be made since it no longer exists as a provisional application.  |

| <u> </u>    | The application(s) to which priority is claimed were filed over a year prior to the filing date of this application. Therefore, the referenced application(s) cannot be claimed as domestic or foreign priority.  |
|-------------|---|
|             | To change the benefit claim of a U.S. prior-filed application, applicant must amend the first sentence of the specification (if the benefit claim is referenced in the specification), or provide a supplemental application data sheet (ADS) (if the benefit claim was submitted in an ADS), with the desired benefit claim. Note that once a benefit claim is deleted, applicant will not be able to claim such prior-filed application again, if the above-identified application was filed on or after November 29, 2000.   |
|             | To change a foreign priority claim, applicant must submit a supplemental oath or declaration (if the priority claim is referenced in the oath or declaration), or a supplemental application data sheet (ADS) (if the priority claim was submitted in an ADS), with the desired priority claim. If a supplemental ADS is submitted, any deletions should be shown with strikeouts. Note that once a priority claim is deleted, applicant will not be able to claim such foreign application again, if the above-identified application was filed on or after November 29, 2000. |
|             | 5 Jamouth   |
| Office of I | Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199, or 1-800-972-6382   |

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FILING OR 371 APPL NO. **ART UNIT** FIL FEE REC'D ATTY.DOCKET NO (c) DATE DRAWINGS TOT CLMS IND CLMS 10/633,204 07/30/2003 3765 1366 A33459-PCT-USA-A (070050. 33 6

21003 BAKER & BOTTS 30 ROCKEFELLER PLAZA NEW YORK, NY 10112 CONFIRMATION NO. 3145
UPDATED FILING RECEIPT
\*OC000000012171688\*

Date Mailed: 03/24/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Shanta M. Modak, River Edge, NJ; Suhas Tambe, Mumbai, INDIA; Lester A. Sampath, Nyack, NY; BAKER BOTTS L.L.P.

04 MAR 29 PM 12: 00

Domestic Priority data as claimed by applicant

This application is a CON of PCT/US02/03087 01/31/2002

Foreign Applications

If Required, Foreign Filing License Granted: 10/30/2003

**Projected Publication Date: 07/01/2004** 

Non-Publication Request: No

Early Publication Request: No

Title

Combinations of antiseptic and antibiotic agents containing medical devices

**Preliminary Class** 

# LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

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APPL NO. FILING OR 371 (c) DATE ART UNIT FIL FEE REC'D ATTY.DOCKET NO DRAWINGS TOT CLMS IND CLMS 10/633,204 07/30/2003 3765 1366 A33459-PCT-USA-A (070050. 33 6

21003 BAKER & BOTTS 30.ROCKEFELLER PLAZA NEW YORK, NY 10112 CONFIRMATION NO. 3145
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Date Mailed: 03/24/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, Check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if

Applicant(s)

Shanta M. Modak, River Edge, NJ; Suhas Tambe, Mumbai, INDIA; Lester A. Sampath, Nyack, NY; BAKER BOTTS L.L.P.

04 MAR 29 PM 12: 00

Domestic Priority data as claimed by applicant

This application is a CON of PCT/US02/03087 01/31/2002 which is a CIP of 09/775,775 02/02/2001 now U.S. Pat. 6,582,719

Foreign Applications

If Required, Foreign Filing License Granted: 10/30/2003

Projected Publication Date: 07/01/2004

Non-Publication Request: No

Early Publication Request: No

Title

Combinations of antiseptic and antibiotic agents containing medical devices

**Preliminary Class** 

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#### **NOT GRANTED**

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